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In The
Supreme Court of the United States

ALBERTO GONZALES, ATTORNEY GENERAL, IN HIS OFFICIAL CAPACITY, ET AL.,

Petitioners,

v.

STATE OF OREGON, ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF AMICUS CURIAE OF THE CATHOLIC MEDICAL ASSOCIATION IN SUPPORT OF PETITIONERS AND IN SUPPORT OF REVERSAL

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INTEREST OF AMICUS[1]

The Catholic Medical Association is a professional association of American and Canadian physicians, who seek to respond to the unique responsibility belonging to all health-care personnel as guardians and servants of human life and human dignity. Its members are conscious of the fact that their patients entrust themselves to the knowledge acquired by physicians. This suggests an important tension. As Pope John Paul, II noted in *On Faith and Reason* (1998), "On the one hand, the knowledge acquired through belief can seem an imperfect form of knowledge, to be perfected gradually through personal accumulation of evidence; on the other hand, belief is often humanly richer than mere evidence, because it involves an interpersonal relationship and brings into play not only a person's capacity to know but also the deeper capacity to entrust oneself to others. . . . " *Id.* at ¶ 32. This capacity to entrust oneself to others lies at the heart of the patient-physician relationship, and at the heart of the patient-physician relationship. The Catholic Medical Association hopes to assist the Court in properly understanding the impact of this case upon that relationship.

SUMMARY OF ARGUMENT

The motivating force behind the Controlled Substances Act was to centralize the enforcement of drug laws to address the national problem of drug abuse. Congress rightly understood that an effective response would require

[1] No counsel for any party authored any portion of this brief. No persons other than amicus curiae, their members, or their counsel have made a monetary contribution to the preparation and submission of this brief. The written consents of the parties will be filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

sensitivity to the legitimate role of the medical profession in fighting disease, restoring health and alleviating human suffering. It would also require uniform characterization, utilization and availability of drugs to be determined at the national level. The Attorney General's construction of the Act and the implementing regulations reflect these Congressional concerns and the reality of contemporary medical practice. In contrast, the position of the Respondents renders the national design of drug approval incoherent and federal enforcement subject to the dictates of state authorities. For these reasons the rulings of the lower courts must be reversed.

ARGUMENT

Federal regulation of drugs is based in part on the reasonable belief that "sick people must be protected from quacks, charlatans, and those who raise false hopes and take advantage of human suffering."[2] The Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-904, furthers society's goal of protecting citizens from both contemporary snake-oil salesmen and drug pushers[3] by directing the Attorney General of the United States to place prescription drugs on a statutory schedule after assessing the drugs for three factors: the drug's potential for abuse, its current accepted medical uses, and the possibility that abuse of the drug will lead to physical or psychological dependency. 21 U.S.C. § 812.

[2] David B. Brushwood, *The Professional Capabilities and Legal Responsibilities of Pharmacists: Should "Can" Imply "Ought"?*, 44 Drake L. Rev. 439, 450 (1996).

[3] *United States v. Moore*, 423 U.S. 122, 143 (1975) (defendant "acted as a large-scale 'pusher' not as a physician."

By including "current accepted medical uses" Congress protected the authentic autonomy of the medical profession. The history of the Federal Food, Drug, and Cosmetic Act reveals that the first bill to pass either house of Congress that was substantially similar to the present Act included within its definition of "drug" the qualification that it did not apply to "the regulation of the legalized practice of the healing art." S. 5, 74th Cong., 1st Sess. § 201(b), 79 Cong. Rec. 8351 (1935). While the definition of "drug" as ultimately enacted did not include this proviso, *see* 21 U.S.C. § 321(g) (1976), the legislative history makes clear that Congress has always sought to protect physicians' ability to treat their patients, while simultaneously insuring the efficacy and safety of drugs. In promulgating 21 C.F.R. § 1306.4(a) the Attorney General also recognized the necessary professional discretion of doctors. "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *Id.*

The present case requires this Court to determine once again whether national or state standards determine legitimate medical practices for purposes of drug regulations. *Cf. United States v. Rutherford*, 442 U.S. 544 (1979) (no exception to FDA approval requirements for Laetrile administered only to terminally ill patients notwithstanding approval by seventeen states) and *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001) (federal law controls over state law regarding the distribution of marijuana).

I. DEFINING "LEGITIMATE MEDICAL PRACTICE" IN TERMS OF NATIONAL PRACTICE IS CONSISTENT WITH THE NORMS OF THE MEDICAL PROFESSION AS EVIDENCED BY PROFESSIONAL STANDARDS REGARDING MEDICAL EDUCATION, LICENSURE, AND THE LIABILITY OF PHYSICIANS.

Defining "legitimate medical practice" by national norms, rather than the isolated practice of a single state is a permissible construction of 21 C.F.R. § 1306.4(a), whether this Court examines the Ashcroft Directive with substantial deference to the judgment of the Attorney General, or under a less deferential standard. *See Oregon v. Ashcroft*, 368 F.3d 1118, 1144 (9th Cir. 2004) (Wallace, J. dissenting). The medical profession, itself, is increasingly adopting national standards for self regulation as evidenced by the pervasive use of a national admissions test for medical school, the Medical College Admission Test, and the universal requirement that students pass the United States Medical Licensing Exam in order to obtain a medical license. *See* Federation of State Medical Boards, *Examinations* at http://www.fsmb. org (visited May 5, 2005). These two tests alone tend to standardize medical school curriculum, since medical students who have successfully competed for their spots in medical school on the basis of a particular test are more likely to bring similar abilities to their medical education. Likewise medical schools insure that their faculty transmits the knowledge and skills that are necessary for students to succeed in passing the United States Medical Licensing Exam since that is the gateway to professional licensure. *See* Steven A. Wartman & John H. Littlefield, *Changes in the US Medical Licensure Examination and Impact on US Medical Schools*, 293 JAMA 424 (2005) (documenting changes in curriculum due to changes in Medical Licensure Exam).

This trend toward national standards is also evident in courts' adoption of a national standard of care for assessing attorney conduct in medical malpractice cases.

> The modern physician bears little resemblance to his predecessors. As we have indicated at length, the medical schools of yesterday could not possibly compare with the accredited institutions of today, many of which are associated with teaching hospitals. But the contrast merely begins at that point in the medical career: vastly superior postgraduate training, the dynamic impact of modern communications and transportation, the proliferation of medical literature, frequent seminars and conferences on a variety of professional subjects, and the growing availability of modern clinical facilities are but some of the developments in the medical profession which combine to produce contemporary standards that are not only much higher than they were just a few short years ago, but also are national in scope.

Shilkret v. Annapolis Emergency Hosp. Assn., 349 A.2d 245, 252 (Md. 1975). *See also Swan v. Lamb*, 584 P.2d 814, 817 (Utah 1978).

As the Tenth Circuit has noted, "The growing majority of jurisdictions employ some variation of the national standard of care: a physician has a duty to employ the same reasonable diligence, skill, competence, and prudence as a minimally competent practitioner in the same general specialty, without regard to whether the care is delivered in an urban or rural setting." *Nadler v. West Park Hosp.*, 254 F.3d 1168, 1176 (10th Cir. 2001).

With the medical profession increasingly relying upon national assessments for those who are entering the profession, and with doctors being held accountable under national standards of care, the Attorney General's use of

national norms to define "legitimate medical practice" is clearly a permissible construction of the regulations regarding the prescribing privileges of physicians.

II. ABUSE OF PRESCRIPTION DRUGS AND THE NEED FOR A UNIFORM DEFINITION OF "LEGITIMATE MEDICAL PURPOSE" FOR ENFORCEMENT PURPOSES SUPPORTS THE INTERPRETATION CONTAINED IN THE ASHCROFT DIRECTIVE.

> Nationwide, the rate of abuse for pharmaceuticals [prescription drugs] is relatively high compared with rates of abuse for other drug types. National Survey on Drug Use and Health (NSDUH) data indicate that 6.3 percent of persons aged 12 or older reported nonmedical use of any prescription-type pain reliever, tranquilizer, stimulant (including both illicit and prescription methamphetamine), or sedative (not including over-the-counter drugs) in 2003, second only to marijuana (10.6%) and much higher than cocaine (2.5%) and heroin (0.1%).

National Drug Intelligence Center, *Pharmaceuticals Drug Threat Assessment* 2 (Nov. 2004). Nearly fourteen percent of young people between the ages of 12 and 17 report having used prescription drugs for non-medical purposes at some point in their lives. National Drug Intelligence Center, *Reducing Prescription Drug Abuse* 1 (2004) at http://www.whitehousedrugpolicy.gov/news/press04/prescrip_fs.pdf (last visited at May 5, 2005). In the past ten years emergency room visits associated with narcotic pain relievers have increased 163%. *Id.* Illegal prescribing by physicians is a significant source of this problem. *Pharmaceuticals Drug Threat Assessment* at 6.

To require the Attorney General to accommodate a state's deviation from common medical practices as demanded by the Respondents in this case risks compounding the existing problem of prescription drug abuse by multiplying the applicable legal standards to be applied by law enforcement in evaluating the conduct of the prescribing physician. This lack of uniformity in drug control laws is one of the very ills that the CSA was intended to eliminate. *O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft*, 389 F.3d 973, 984 (10th Cir. 2004) (Murphy J. concurring in part and dissenting in part) (congressional findings in CSA speak to a need for uniformity in administration given the serious problem of drug abuse in the United States). The Attorney General's use of a uniform standard of "legitimate medical practice" for physicians prescribing controlled substances in all states is clearly a permissible construction of the regulations under the CSA.

III. THE STATUTORY DEFINITION OF DRUGS SUBJECT TO PRESCRIPTION WOULD BE RENDERED NONSENSICAL BY INCLUDING ASSISTING WITH SUICIDE AS A "LEGITIMATE MEDICAL PURPOSE."

In *Whalen v. Roe*, the Court stated, "It is, of course, well settled that the State has broad police powers in regulating the administration of drugs by the health professions." 429 U.S. 589, 603 n.30 (1977), citing *Robinson v. California*, 370 U.S. 660, 664-665 (1962); *Minnesota ex rel. Whipple v. Martinson*, 256 U.S. 41, 45 (1921); and *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1954). "Although the State no doubt could prohibit entirely the use of particular Schedule II drugs, it has not done so." *Id.* at 603. Schedule II drugs "have accepted uses in the amelioration of pain and in the treatment of [various diseases]" (*id.* at 593 n.8); they are safe and effective, but

are also liable to abuse. If a state may prohibit entirely the use of such drugs, then surely the government may restrict the circumstances of their use.

The contours of this case are deceptively narrow. The claim urged at present is only in support of a judgment that prohibits the federal government from interfering with access by Oregon physicians assisting terminally ill patients in accordance with that state's law. But the logic of the claim goes much further. If, as the lower courts held, state law determines the right of access to any drug, then it is difficult to see how the CSA can be enforced with respect to any drug if a state chooses to legislate to the contrary.

This Court confronted a similar issue in *United States v. Rutherford*, 442 U.S. 544 (1979) when reviewing a lower court decision that exempted the drug Laetrile from FDA approval when used by terminally ill cancer patients. Seventeen states had legalized the use of Laetrile for cancer treatment, notwithstanding the fact that the drug had not been approved by the FDA. *Id.* at 554, n. 10. The lower court had ruled that the FDA requirements of safety and effectiveness had no reasonable application to terminally ill patients, and thus doctors were free to prescribe it for cancer patients who were dying. *Id.* at 551.

In reversing the court of appeals, this Court observed, "To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner's authority over all drugs, however toxic or ineffectual, for such individuals." Similarly, to accept Respondents' characterization of assisting suicide as a "legitimate medical purpose" is to render virtually meaningless the safety and efficacy analysis engaged in by the FDA

when evaluating drugs.[4] The Oxford English Dictionary defines safety as "exemption from hurt or injury." OXFORD ENGLISH DICTIONARY (2d ed. 1989). If inducing death is a legitimate use of the drug under consideration, how is the safety of that drug to be assessed? Does death become merely a possible adverse side effect for some uses, or is it simply another indicated use?

As this Court so presciently noted in the *Rutherford* case:

> If history is any guide, this new market would not be long overlooked. Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer, including liniments of turpentine, mustard, oil, eggs, and ammonia; peat moss; arrangements of colored floodlamps; pastes made from glycerin and limburger cheese; mineral tablets; and "Fountain of Youth" mixtures of spices, oil, and suet. In citing these examples, we do not, of course, intend to deprecate the sincerity of Laetrile's current proponents, or to imply any opinion on whether that drug may ultimately prove safe and effective for cancer treatment. But this historical experience does suggest why Congress could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise.

442 U.S. at 558.

Similarly, if Respondents prevail in this case, lethal substances suddenly become candidates for a new category

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[4] *Cf.* David B. Brushwood, *The Professional Capabilities and Legal Responsibilities of Pharmacists: Should "Can" Imply "Ought"?*, 44 Drake L. Rev. 439, 448-52 (1996).

of controlled substances to be marketed to physicians and patients for suicides. Just as Dr. Kevorkian found patients for his suicide machine before he was enjoined from using it, other enterprising purveyors of death will no doubt seek to capitalize on the suffering of the terminally ill. *See People ex rel. Oakland County Prosecuting Atty. v. Kevorkian*, 534 N.W.2d 172 (Mich. App., 1995).

CONCLUSION

The Attorney General's construction of the CSA and its implementing regulations is consistent with the medical profession's increasing reliance on national norms for self-regulation, is an integral part of the enforcement of the laws prohibiting abuse of prescription drugs, and is a necessary construction to retain any coherent regulatory authority over the safety of prescription drugs. For all the foregoing reasons, Amicus respectfully urges this Court to reverse the judgment of the courts below.

Respectfully submitted,

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